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RESEARCH

Chronic pain following totally extra-peritoneal inguinal hernia repair: a randomized clinical trial comparing glue and absorbable tackers

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Abstract

Purpose Chronic pain following inguinal hernia repair occurs in up to 20% of patients. The underlying mechanism probably involves sensory nerve damage and abnormal healing that might be influenced by the materials chosen for mesh fixation. The main objective of this study was to compare glue and absorbable tackers on the rate of chronic pain after surgery in patients undergoing totally extraperitoneal inguinal hernia repair (TEP).

Methods Patients undergoing (TEP) inguinal hernia repair were enrolled in a single-blind randomized clinical trial and were randomized for mesh fixation with glue (LIQUIBAND FIX 8 Neopharm) or absorbable tackers (SECURE STRAP Johnson & Johnson). Pain was assessed using a validated 4-point verbal-rank scale (none, mild, moderate, and severe) at 1 week, 1 month, 6 months, and 1 year postoperatively. Chronic pain was defined as pain persisting beyond 3 months.

Results Two hundred and eight patients were analyzed. The groups were similar in age, gender, and hernia side. Chronic pain of any intensity was reported in 31.7% (66/208) after 6 months and in 13% (29/208) after 12 months. No differences in postoperative pain were observed between the two forms of mesh fixation. Still, when only those with severe pain were considered, mesh fixation with glue resulted in less pain compared to fixation by tackers (log-rank $p = 0.025$). At 1 year, 4 symptomatic recurrent hernias were identified in patients whose mesh was fixated with absorbable tackers.

Conclusions Patients who underwent TEP inguinal hernia repair with mesh fixated by glue suffered from less pain.

Keywords Inguinal hernia · Endoscopic hernia repair · Chronic pain

Background

Inguinal hernia is one of the most common surgical pathologies. Postoperative chronic inguinal pain has been reported in 16–62% of patients who undergo inguinal hernia repair [1]. Prevalence of groin pain has been significantly decreased with the adoption of the endoscopic approach, but up to 20% of the patients undergoing laparoscopic repair may still suffer from chronic pain [2]. Although postoperative groin pain is usually mild in nature, quality-of-life studies have shown that chronic pain may significantly interfere with normal daily activity [1, 3]

The underlying pathogenesis of postoperative groin pain is not completely clear; it may be multifactorial and, in many cases, impossible to define. One possible explanation relates to nerve damage during surgery, but this seems not to be the only factor, as many patients have postoperative sensory diminution without pain [1]. Another commonly cited reason may be associated with chronic foreign body inflammatory response due to the use of mesh [2]. The synthetic mesh is secured to the abdominal wall by tackers or glue [4], which may also potentially influence postoperative pain. The assumption is that tackers that are encored into the tissue, such as pubic bone or abdominal wall muscles, may result in a higher rate of local response and in higher rate of postoperative chronic pain compared to fixation methods that are not encored into the tissue. A recent network meta-analysis suggests that absorbable tacks and glue cause less local tissue response and may be associated with

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the lowest rate of chronic pain and recurrence [5]. It is for that reason we decided to compare these two techniques in a randomized trial.

The main aim of this study was to assess the effect of two methods for mesh fixation in TEP inguinal hernia repair, absorbable tackers vs. glue, on postoperative chronic pain.

Methods

Design

We performed a single-blind, randomized clinical trial comparing mesh fixation using glue to mesh fixation using absorbable tack staples in patients undergoing TEP hernia repair.

Ethical committee approval

The study was approved by the local Institutional Review Board (193-16-ASF), and all patients gave their written informed consent.

Participants

Patients aged 18 to 80 years old who were admitted for elective inguinal hernia repair between March 1, 2017, and March 30, 2020, were eligible to participate in the study. Patients with a recurrent, irreducible, or incarcerated hernia, large inguinoscrotal hernia, pregnant women, patients presenting with co-morbid conditions that might interfere with pain assessment (impaired cognitive status, limited mobility, and daily use of pain medicine), and patients with previous surgery in the groin were excluded from the study. Patient's flowchart is shown in Fig. 1.

Randomization

Randomization was made using sealed envelopes, which were opened in the operating room just before mesh fixation.

Intervention

In group I, mesh was secured by glue (LIQUIBAND FIX 8, Liquiband, Advanced Medical Solutions, UK), and group II included patients with mesh secured to the tissue by

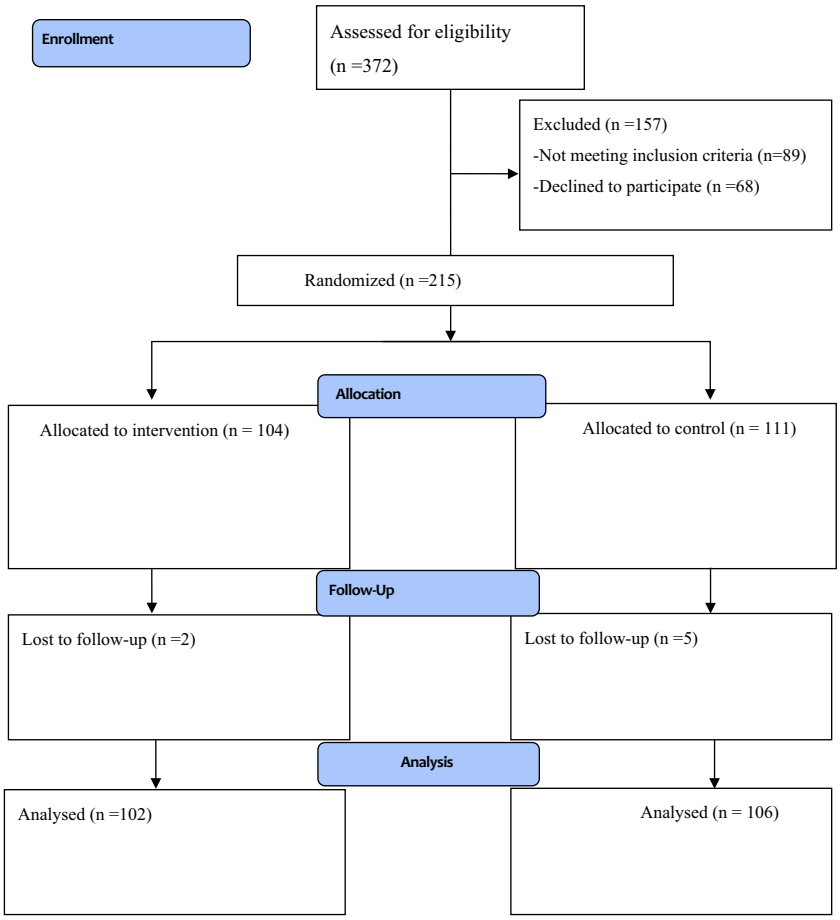

Fig. 1 Participants' enrollment flowchart

absorbable tackers (SECURE STRAP, Johnson & Johnson, USA). Surgery was performed under general anesthesia by 5 attending surgeons with individual experience in more than 200 laparoscopic inguinal hernia repairs. A standard, uniform surgical technique of TEP inguinal hernia repair was applied in all cases. All patients received prophylactic antibiotics with 2 g of intravenous cefazolin before surgery. The TEP inguinal hernia repair was routinely done using 3 trocars, with the camera having an 11-mm port at the umbilical border and two 5 mm ports along the midline about 4 cm and 8 cm above the pubis. Pre-peritoneal balloons were not used to dissect the pre-peritoneal space in this study. An appropriately sized knitted polypropylene mesh (Bard 3Dmax, BD, USA) was used in all patients. The mesh fixation points were standardized for all participants. The mesh was secured medially, just above the pubic bone, into Cooper's ligament and to the back of the transverse fascia laterally (maximum of 4 tackers or glue applications) [6].

Patients were discharged from the hospital within 24 h following surgery. Standard postoperative care instructions were given by staff nurses, who were blinded to the randomization.

Outcomes

All patients were examined in the outpatient clinic at 7 days and 1 year after surgery. A telephone interview was also performed at 1 month, 3 months, and 6 months after surgery. The examinations and telephone interviews were performed by an attending surgeon blinded to the method of mesh fixation. All the interview questions were standardized. Pain was assessed using a 4-point verbal-rank scale [7]. Patients were asked about the degree of pain, use of pain medications, restriction of daily activity, and use of medical resources such as medical consult for inguinal pain. Mild pain was defined as occasional pain or discomfort that did not limit daily activity and did not require pain medications, moderate pain interfered with normal daily activity with rare analgesic requirement, and severe pain was incapacitating, at frequent intervals, or interfering with daily activities with a frequent need for painkillers. Daily activity included both physical and sport activities such as walking, lifting a bag, or jogging. Chronic pain was defined as pain persisting beyond 3 months after surgery [7].

Statistical analysis

Statistical analysis was performed with R version 4.1.0 (R Foundation for Statistical Computing) and GraphPad Prism (version 6.00 for Windows, GraphPad Software, La Jolla, California, USA). Descriptive statistics were presented with mean (standard deviation) or number (percentage) for continuous and categorical covariates, respectively. Comparisons between the two groups were analyzed with independent t-tests and χ^2-tests for continuous and categorical variables, respectively. Time-to-event curves were constructed for each of the groups for residual pain. The log-rank test was used to test the differences between the time-to-event curves. Means, standard deviation, and percentages were approximated to the nearest decimals, and p-values to the nearest thousandth.

Results

Recruitment data

Three hundred and seventy-two patients who underwent laparoscopic TEP inguinal hernia repair at the Shamir Medical Center during the study period were screened for this study. Eighty-nine of them did not meet the inclusion criteria, and 68 patients refused to participate. Two hundred fifteen patients (199 males and 16 females) were randomly assigned to the 2 study groups. Seven patients were lost for follow-up and were excluded from the final analysis. Figure 1 summarizes the study flowchart from eligibility assessment to final analysis.

Seventeen patients were unable to visit the outpatient clinic for examination 1 year after surgery due to COVID-19 pandemic restrictions. These patients were interviewed by telephone regarding pain and were considered minor protocol deviation.

Baseline characteristics

Two hundred and eight patients participated in the study and underwent 346 laparoscopic TEP repairs, including 70 patients who underwent unilateral and 138 bilateral hernia repairs. No significant differences were observed in age and gender distribution between the groups (Table 1). Overall, 17 patients were unable to visit the outpatient clinic for physical examination 1 year after surgery (8 from group 1 and 9 from group 2).

Table 1 Baseline characteristics

		Group I	Group II	*P*-value
Age	Mean (SD)	54.5 (16.3)	54.5 (16.0)	0.972
Gender	Male	96 (94.1%)	99 (93.4%)	1.000
	Female	6 (5.9%)	7 (6.6%)	
Sides	Unilateral	34 (33.3%)	36 (34.3%)	1.000
	Bilateral	68 (66.7%)	70(65.7%)	
Hernia type	Direct	43 (25.1%)	49 (27.8%)	0.34
	Indirect	120 (70.2%)	113 (64.2%)	
	Pantaloon	8 (4.7%)	14 (8.0%)	
Large hernia		10 (5.8%)	13 (7.4%)	0.67
Lipoma		31 (18.1%)	36 (20.5%)	0.59

Postoperative pain assessment

Residual pain following surgery of any intensity was reported in 54.8% (114/208) after 1 month, 31.7% (66/208) after 6 months, and 13% (29/208) after 12 months (Fig. 2). When the patients were stratified according to the technique of mesh fixation, no difference in moderate to severe residual pain was observed (Fig. 3). Severe pain after surgery was infrequent and declined from 11% of the patients 1 week after surgery to 1% 1 year later. At each time point, there were less patients suffering from severe pain when mesh fixation was made with the glue compared to tack fixation (log-rank $p = 0.025$) (Fig. 4).

Postoperative complications and hernia recurrences

Two patients from group 1 developed urinary retention, and one patient from group 2 was readmitted due to large inguinoscrotal hematoma. No wound-related complications were observed.

Ten out of 329 recurrent unilateral hernias were diagnosed (3%), 1 patient from the glue fixation group and 9 from the tacker fixation group ($p = 0.02$). Patients with recurrence were older (70 ± 8), and two of them were female. Eight patients had indirect hernia on the first surgery. Nine patients initially underwent bilateral indirect inguinal hernia repair. Four patients from group 2 underwent surgery due to symptomatic recurrence. All symptomatic recurrent hernias were diagnosed in the first 4 months after surgery. Asymptomatic recurrent inguinal hernia was diagnosed by physical examination and confirmed by ultrasonography in 6 patients.

Discussion

The main aim of this study was to evaluate whether the form of mesh fixation may affect chronic pain. Overall, no differences in chronic pain were found between patients who underwent mesh fixation with glue and those who underwent fixation with tackers. Our results do show that patients in whom mesh was fixed by glue had a lower probability of suffering from severe chronic pain. These results suggest that mesh fixation with glue may be superior in patients undergoing TEP hernia repair.

Laparoscopic TEP inguinal hernia repair is a standard practice today. In a large cohort study based on the Swedish national hernia registry, Lindstrem et al. showed a significant decrease in chronic groin pain after TEP repair compared with open repair, at the cost of increased risk of recurrence requiring surgery [8].

Mesh is traditionally used to cover hernia defects. Many surgeons routinely fix the mesh to the tissue to avoid its displacement. Several authors recommended proper mesh placement in preperitoneal space with no fixation in order to avoid additional tissue damage and decrease the rate of chronic pain [9]. In a randomized control trial (RCT), Moreno-Egea et al. showed no difference in the rate of chronic pain when comparing mechanical mesh fixation with non-fixation technique [10].

Different types of mesh fixation have been proposed, varying from mechanical staples or tacks and glue to simple sutures, but high-quality evidence for differences between mesh fixation techniques and their influence on chronic pain is still lacking.

Most of the RCTs were either based on small number of patients or included a mix of TEP and transabdominal preperitoneal repair.

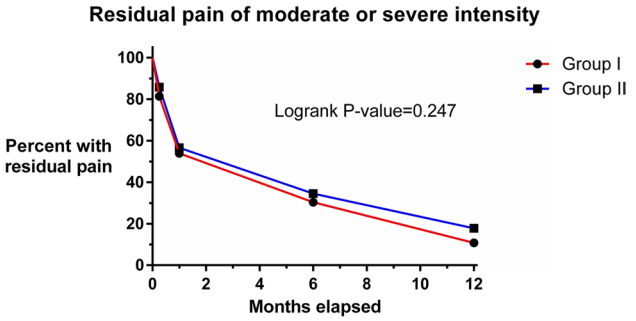

Fig. 3 Residual pain moderate and severe intensity

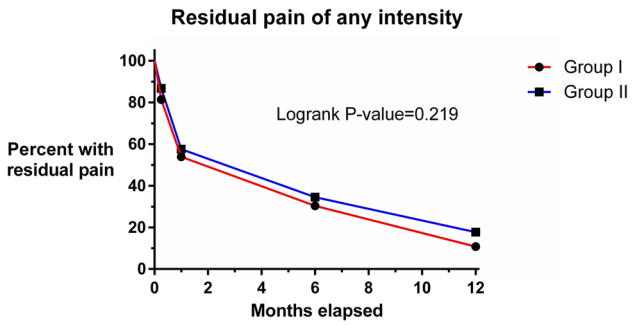

Fig. 2 Residual pain any intensity

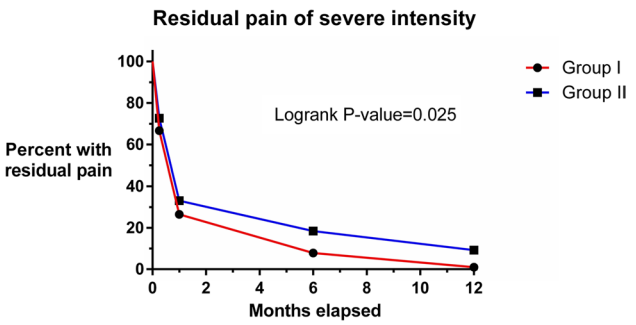

Fig. 4 Residual pain severe intensity

Chronic groin pain appears in 1–20% of patients after laparoscopic inguinal hernia repair [4]. Techapongsatorn et al. recently evaluated 11 RCTs and found no significant difference between various types of mesh fixation for laparoscopic hernia repair, but ranked glue as the best method for less chronic pain [5]. Chih-Chin Yu et al. prospectively studied single institution data of 583 patients after TEP repair [11] and found higher rate of acute groin pain in patients with mechanical fixation compared to the glue. However, chronic groin pain rate was similar between the groups.

Recurrent inguinal hernia after laparoscopic repair appears in 1 to 13% of the patients [4, 12]. These figures probably underestimated the real recurrence rate as many studies did not actively follow their patients in the long run, and patients were actively examined only if they experienced symptoms of recurrent hernia. All but 17 patients in our study were examined by attending surgeons blinded to study randomization 1 year after surgery. Indeed, only 4 patients had a symptomatic recurrence. Six patients had no symptoms of recurrence, diagnosed by physical examination as part of the follow-up protocol and confirmed by ultrasonography. Recurrent hernia in our study was significantly more common in patients in whom the mesh was secured using absorbable trackers compared to those where the mesh was secured with glue, suggesting an additional benefit for the glue. The reason for this difference is not completely clear, as both methods should secure the mesh in place in the pre-peritoneal space during the initial healing phase to allow fibrosis. The use of tackers may require more precise application at the pubic bone to ensure appropriate anchoring. We standardized the technique of mesh securing, and all the attending surgeons participating in the study were highly experienced in the use of tackers for laparoscopic hernia repair, and it seems unlikely that misuse of the tackers can explain this difference.

The study is an investigator-initiated trial that was not supported by any of the industrial companies, and both products were readily available for the use of surgeons in our Institute. This limits potential publication bias and other potential biases that may be associated with sponsored studies.

Our study has certain limitations that might influence the final conclusions. A non-response bias or loss for follow-up might have occurred in this study, which was affected by the COVID-19 pandemic and may have weakened our observed differences. A larger study sample size could have observed a more accurate picture of the pain assessment and postoperative complication rate. Furthermore, in this study, we focused only on pain and its interference with daily activities. We did not evaluate other outcomes related to quality of life.

In conclusion, this study shows that the use of glue for mesh fixation decreases severe groin pain and hernia recurrence in patients undergoing laparoscopic TEP hernia repair compared to absorbable tackers.

Author's contributions Study conception and design: Jeroukhimov and Dykman. Acquisition of data: Nesterenko, Poluksht, Ben Yehuda, Stephansky, and Jeroukhimov. Analysis and interpretation of data: Jeroukhimov and Hershkovitz. Drafting of the manuscript: Jeroukhimov and Hershkovitz. Critical revision: Jeroukhimov and Zmora.

Declarations

Conflict of interest The authors declare no competing interests.

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